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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/802,315	03/08/2001	Archie Woodworth	1417 Y P 516	5264

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EXAMINER	
MCKANE, ELIZABETH L	
ART UNIT	PAPER NUMBER
1744	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/802,315	WOODWORTH ET AL.	
	Examiner	Art Unit	
	Leigh McKane	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *109-136* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *109-136* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 March 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 19 January 2007 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 120 and 132 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 120 and 132 both recite that the plunger is inserted into an open end of each container prior to introducing a sterile fluid substance into the container. However, the specification clearly teaches that the syringe is filled and then the plunger is inserted into the syringe. See page 3, lines 13-18.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 109-114, and 115 are rejected under 35 U.S.C. 103(a) as being unpatentable over Erbe et al. (U.S. Patent No. 6,800,245).

With respect to claims 109, 110, and 112-115, Erbe et al. teaches a method of producing a plurality of sterilized, prefilled containers wherein the method includes providing a manufacturing line with at least one container, transferring the container to a sterile environment (isolator) **70**, and sterilizing the cartridge with e-beam radiation (which would create an immediate sterile ambient atmosphere) in a step between providing the cartridges and transferring them to the sterile environment. Within the sterile environment, they are filled and sealed, and finally are transferred out of the sterile environment at **90**. See Figure 1; col.4, lines 34-37; col.6, lines 3-20; col.8, lines 17-20 and 30-32; col.12, lines 2-5, 19-27, 39-46. Erbe et al. does not disclose a plurality of separate manufacturing lines, each having it's own sterilizing station. However, it has been held that to duplicate parts for multiplied effect, where the result is not unexpected, is obvious. See St. Regis Paper Co. v. Bemis Co., Inc., 193 USPQ 8, 11 (7th Cir. 1977). In this case, the result of duplicating the single manufacturing line of Erbe et al. is readily apparent to one of ordinary skill in the art – the increase in number of manufacturing lines

entering the sterile environment, increases the number of syringes that may be sterilized, filled, and sealed in a given plant.

As to claim 111, Erbe et al. clearly teaches that the cartridges (syringes) are sterilized in a location other than the sterile isolator. Note that Erbe et al. discloses that only the steps of filling, assembling the piston, packaging the filled cartridges, and sealing the packages occur in the sterile isolator. See col.6, lines 14-18. Therefore, the cartridges *must* be transferred between the location where they are sterilized by e-beam radiation and the location where they are filled (isolator). It would have been obvious to one of ordinary skill in the art to accomplish this transfer in a sterile manner otherwise the sterile condition of the cartridges would have been compromised.

6. Claims 116-117 are rejected under 35 U.S.C. 103(a) as being unpatentable over Erbe et al. in view of Carlsson et al. (US 4,944,132).

Erbe et al. discloses the use of e-beam radiation for the sterilization of the containers, but does not teach the use of a plurality of beams or opposing beams on opposite sides of a transport mechanism. Carlsson et al. evidences the use of e-beam radiation for the sterilization of containers wherein a transport mechanism **4,13,24** conveys the containers between opposing e-beam units **8**. See Figure 3. Carlsson et al. discloses that using two electron beam units assures complete sterilization of all surfaces of the container (col.3, lines 42-68). Therefore, it would have been obvious to employ the transport and sterilization means of Carlsson et al. to sterilize the containers of Erbe et al. in order to completely sterilize all surfaces thereof.

7. Claims 118-124 are rejected under 35 U.S.C. 103(a) as being unpatentable over Erbe et al. in view of Odell et al. (US 6,189,292).

With respect to claims 118-121, the containers of Erbe et al. do not have tip caps that are placed on the container prior to filling or plungers that are assembled onto the containers after filling. Odell et al., however, discloses a method of manufacturing, sterilizing, filling, and sealing medical syringes wherein tip caps are coupled to the syringe before filling and the plunger is used to seal the filled syringe. Alternatively, the plunger can be first coupled to the syringe, the syringe filled through the tip, and the syringe sealed with the tip cap. See col.12, line 44 to col.13, line 25. It would have been obvious to use the method of Erbe et al. to sterilize other types of containers, such as the syringe systems of Odell et al., as Erbe et al. discloses that it is en effective means of producing a variety of sterilized components including at least one radiation-sensitive composition unsuitable for terminal sterilization, as these compositions are dispensed from syringes as well as the containers of Erbe et al. See col.3, lines 55-60.

As to claims 122 and 123, Erbe et al. fails to teach a molding station. Nevertheless, Odell et al. discloses a method wherein a molding machine **220** may be located adjacent the filling and sealing assembly and connected thereto by a closed conveyor, tunnel or chute to form an environmentally controlled area for transfer of the syringes. See col.12, lines 24-29. It would have been obvious to one of ordinary skill in the art at the time of the invention to include a molding station as a component of the manufacturing line of Erbe et al., as Odell et al. discloses that doing so maintains low bio-burden levels by reducing the handling of the syringes. In addition, one would have found it obvious to include a molding machine in each manufacturing line, in order to produce various types of syringes.

With respect to claim 124, although Erbe et al. is silent with respect to a transfer holder for the containers, Odell et al. discloses a transfer holder **82** for holding a plurality of syringes. As the holder is designed for ease of handling through the manufacturing line of Odell et al., it would have been an obvious addition to the method of Erbe et al..

8. Claim 125 is rejected under 35 U.S.C. 103(a) as being unpatentable over Erbe et al. in view of Lawecki et al. (US 6,145,277).

It is unclear from the disclosure of Erbe et al. if the manufacturing process is fully automated. However, Lawecki et al. teaches a method of in-line, continuous production of sterile, prefilled syringe bodies wherein the method includes the steps of injection molding the syringe bodies (col.2, lines 12-13), arranging the syringe bodies on a conveyor (col.2, lines 15-17), sterilizing the syringe bodies using a sterilizing gas (col.2, lines 3-5), transferring the syringe bodies to an inspection station and a filling and assembly isolation area followed by a packaging station. See col.2, lines 26-36 and lines 42-48. Lawecki et al. further discloses that "preferably no humans are employed" as the process is substantially automated or accomplished by robots. As automating the process makes sense from both an economical, as well as, a hygienic standpoint, it would have been obvious to automate the process of Erbe et al..

9. Claims 126 and 127 are rejected under 35 U.S.C. 103(a) as being unpatentable over Erbe et al. in view of Nablo et al. (U.S. 3,780,308).

Erbe et al. teaches a method of producing a sterilized, prefilled container wherein the method includes providing a container, sterilizing the cartridge with e-beam radiation at a sterilizing station (which would create an immediate sterile ambient atmosphere), transferring the container to a sterile environment (isolator) **70** separate from the sterilizing station, and

sterilizing the cartridge with e-beam radiation. Within the sterile environment, they are filled and sealed, and finally are transferred out of the sterile environment at **90**. See Figure 1; col.4, lines 34-37; col.6, lines 3-20; col.8, lines 17-20 and 30-32; col.12, lines 2-5, 19-27, 39-46. Erbe et al. clearly teaches that the cartridges (syringes) are sterilized in a location other than the sterile isolator. Note that Erbe et al. discloses that only the steps of filling, assembling the piston, packaging the filled cartridges, and sealing the packages occur in the sterile isolator. See col.6, lines 14-18. Therefore, the cartridges *must* be transferred between the location where they are sterilized by e-beam radiation and the location where they are filled (isolator). It would have been obvious to one of ordinary skill in the art to accomplish this transfer in a sterile manner otherwise the sterile condition of the cartridges would have been compromised. Erbe et al., however, does not disclose a transport mechanism from the sterilizing station into the sterile environment.

Nablo et al. however discloses the use of a transport mechanism **8** for conveying containers through a sterilizing station. Since it is evident that some sort of transport mechanism would have been necessary in Erbe et al. in order to convey the cartridges through the manufacturing process, it would have been obvious to employ a transport mechanism suitable for use in an electron-beam radiation environment, such as that of Nablo et al..

10. Claims 128 and 129 are rejected under 35 U.S.C. 103(a) as being unpatentable over Erbe et al. and Nablo et al. as applied to claim 127 above, and further in view of Carlsson et al. (US 4,944,132).

Erbe et al. discloses the use of e-beam radiation for the sterilization of the containers, but does not teach the use of a plurality of beams or opposing beams on opposite sides of a transport

mechanism. Carlsson et al. evidences the use of e-beam radiation for the sterilization of containers wherein a transport mechanism **4,13,24** conveys the containers between opposing e-beam units **8**. See Figure 3. Carlsson et al. discloses that using two electron beam units assures complete sterilization of all surfaces of the container (col.3, lines 42-68). Therefore, it would have been obvious to employ the transport and sterilization means of Carlsson et al. to sterilize the containers of Erbe et al. in order to completely sterilize all surfaces thereof.

11. Claims 130-135 are rejected under 35 U.S.C. 103(a) as being unpatentable over Erbe et al. and Nablo et al. as applied to claim 126 above, and further in view of Odell et al..

With respect to claims 130-133, the containers of Erbe et al. do not have tip caps that are placed on the container prior to filling or plungers that are assembled onto the containers after filling. Odell et al., however, discloses a method of manufacturing, sterilizing, filling, and sealing medical syringes wherein tip caps are coupled to the syringe before filling and the plunger is used to seal the filled syringe. Alternatively, the plunger can be first coupled to the syringe, the syringe filled through the tip, and the syringe sealed with the tip cap. See col.12, line 44 to col.13, line 25. It would have been obvious to use the method of Erbe et al. to sterilize other types of containers, such as the syringe systems of Odell et al., as Erbe et al. discloses that it is en effective means of producing a variety of sterilized components including at least one radiation-sensitive composition unsuitable for terminal sterilization, as these compositions are dispensed from syringes as well as the containers of Erbe et al. See col.3, lines 55-60.

As to claim 134, Erbe et al. fails to teach a molding station. Nevertheless, Odell et al. discloses a method wherein a molding machine **220** may be located adjacent the filling and sealing assembly and connected thereto by a closed conveyor, tunnel or chute to form an

environmentally controlled area for transfer of the syringes. See col.12, lines 24-29. It would have been obvious to one of ordinary skill in the art at the time of the invention to include a molding station as a component of the manufacturing line of Erbe et al., as Odell et al. discloses that doing so maintains low bio-burden levels by reducing the handling of the syringes.

With respect to claim 135, although Erbe et al. is silent with respect to a transfer holder for the containers, Odell et al. discloses a transfer holder **82** for holding a plurality of syringes. As the holder is designed for ease of handling through the manufacturing line of Odell et al., it would have been an obvious addition to the method of Erbe et al..

12. Claim 136 is rejected under 35 U.S.C. 103(a) as being unpatentable over Erbe et al. and Nablo et al. as applied to claim 126 above, and further in view of Lawecki et al..

It is unclear from the disclosure of Erbe et al. if the manufacturing process is fully automated. However, Lawecki et al. teaches a method of in-line, continuous production of sterile, prefilled syringe bodies wherein the method includes the steps of injection molding the syringe bodies (col.2, lines 12-13), arranging the syringe bodies on a conveyor (col.2, lines 15-17), sterilizing the syringe bodies using a sterilizing gas (col.2, lines 3-5), transferring the syringe bodies to an inspection station and a filling and assembly isolation area followed by a packaging station. See col.2, lines 26-36 and lines 42-48. Lawecki et al. further discloses that "preferably no humans are employed" as the process is substantially automated or accomplished by robots. As automating the process makes sense from both an economical, as well as, a hygienic standpoint, it would have been obvious to automate the process of Erbe et al..

Response to Arguments

13. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Inasmuch as they may apply to the instant rejection, Applicant's comments concerning Erbe et al. will be addressed. Applicant argues that there "is certainly no teaching or suggestion that the pre-sterilizing stage may be used to provide at least a portion of a sterile ambient atmospheric condition external and adjacent to the sterile environment." However, the e-beam radiation station of Erbe et al. would have intrinsically created a sterile environment within the area of sterilization, which also external to the sterile environment.

Conclusion

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh McKane whose telephone number is 571-272-1275. The examiner can normally be reached on Monday-Friday (5:30 am-2:00 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leigh McKane

Leigh McKane
Primary Examiner
Art Unit 1744

elm
28 February 2007